

94. (Previously Added) The pharmaceutical composition of claim 93, wherein the hydroxylation is proline hydroxylation.
95. (Previously Canceled)
96. (Previously Canceled)
97. (Previously Canceled)
98. (Currently Amended) A pharmaceutical composition comprising a recombinant human gelatin and a pharmaceutically acceptable excipient, wherein the recombinant human gelatin is produced directly ~~from an altered collagen construct~~ by expression of a polynucleotide sequence that contains at least one collagenous domain and that does not encode naturally occurring collagen.

Please add new claim 99:

99. (Added herein) A recombinant gelatin consisting of recombinant gelatin polypeptides of a uniform molecular weight.

REMARKS

Justification for the amendments is as follows. Support for the amendment to claim 3 is found, for example, at page 32, line 10, of the specification as filed. Support for amended claims 4, 12, and 90 is found throughout the specification, for example, at page 31, line 27. Claims 89 and 98 as amended are supported, e.g., at page 23, lines 20-23, of the specification. The recombinant gelatin of new claim 99 finds support throughout the specification, at least at, for example, page 31, line 27. Examiner Kam and Examiner Weber's indication that these claims would be allowable as amended herein is much appreciated. The remaining amendments to the claims were made to further clarify the present invention. No new matter is added by any of the above amendments.

I. Claim Status

Claims 1-74 were originally filed, and were subject to restriction. In response to the Restriction Requirement dated 09 July 2001, Applicants elected with traverse the claims of Group I, claims 1-21, 30, and 42-74. In the Amendment dated 16 August 2002, claims 1, 22-29, 31-41, 52, and 63 were canceled without prejudice to their renewal and claim 75 was added. In the Amendment dated 24 June 2003, claims 16-20, 46, 53, and 74 were canceled without prejudice to their renewal and claims 76-98 were added. In the Amendment dated 15 March 2004, claims 9, 13, 14, 15, 42, 49, 51, 58, 60, 84, 85, 86, 87, 88, 91, 95, 96, and 97 were canceled without prejudice to their renewal.

Claims 2, 3, 4, 5, 6, 8, 12, 76, 77, 78, 79, 80, 81, 82, 83, 89, 90, 92, 93, and 98 are amended herein, and new claim 99 is added. Therefore, claims 2-6, 8, 12, 21, 30, 43-45, 47, 48, 50, 54-57, 59, 61, 62, 64-68, 70-73, 75-83, 89, 90, 92-94, 98, and 99 are pending. In the Office Action dated 09 June 2004, the Examiner indicated that claims 5, 6, 30, 43-45, 47, 48, 50, 54-57, 59, 62, 64-68, 70-73, 76-83, and 92-94 are allowable.

II. Rejection of claims 2, 3, 8, 12, 21, 61, 75, and 98 under the doctrine of obviousness-type double patenting

The Examiner provisionally rejected claims 2, 3, 8, 12, 21, 61, 75, and 98 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 12-18, and 47-48 of copending U.S. Patent Application Serial No. 10/232,175. Applicants note that a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) was filed in association with commonly owned and copending U.S. Patent Application No. 10/232,175, a copy of which terminal disclaimer is attached to this Amendment for the Examiner's convenience. As a terminal disclaimer was filed in association with copending U.S. Patent Application Serial No. 10/232,175, the provisional rejection of claims 2, 3, 8, 12, 21, 61, 75, and 98 under the judicially created doctrine of obviousness-type double patenting is thus moot. Withdrawal of the rejection of these claims under the judicially created doctrine of obviousness-type double patenting is therefore respectfully requested.

III. Rejection of claims 3, 89, and 98 under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 3, 89, and 98 under 35 U.S.C. § 112, second paragraph. With respect to claim 3, the Examiner stated that the term "about 0 to 50 kDa" rendered the claim indefinite. (See Office Action, page 5, subsection 12.) The term "about 0 to 50 kDa" does not appear in amended claim 3 above. With respect to claims 89 and 98, the Examiner stated that the term "altered collagen construct" rendered these claims indefinite. (Office Action, page 5, subsection 13.) Applicants submit that the term "altered collagen construct" as recited in claims 89 and 98 would be understood by a person of skill in the art in view of the specification, at least for the reasons earlier described. However, in order to expedite prosecution of the present application, the term "altered collagen construct" does not appear in the claims as amended. Specifically, claims 89 and 98 are amended above to recite that the claimed recombinant gelatins are "produced directly by expression of a polynucleotide sequence that contains at least one collagenous domain and that does not encode naturally occurring collagen." The Examiners' indication in the interview of 7 December 2004 that the above amendments to claims 3, 89, and 98 would overcome the rejection of these claims under 35 U.S.C. § 112, second paragraph, is appreciated. In view of the above discussion, withdrawal of the rejection of these claims under 35 U.S.C. § 112, second paragraph, is respectfully requested.

IV. Rejection of claims 4, 12, and 90 under 35 U.S.C. § 102(e)

The Examiner rejected claims 4, 12, and 90 under 35 U.S.C. § 102(e) as being anticipated by Wunderlich et al. (U.S. Patent No. 6,068,854).

Wunderlich describes microencapsulation of a pharmaceutical substance using a mixture of different gelatin types, and states that a "particularly homogeneous distribution of the microencapsules" can be obtained using a mixture of different gelatin types "with identical or similar molecular weight distribution." (See Wunderlich, column 8, lines 33-36.) Claim 4 as amended above is directed to a recombinant gelatin composition "consisting essentially of recombinant gelatin polypeptides of a uniform molecular weight, wherein the uniform molecular weight is greater than 300 kDa." Wunderlich does not disclose recombinant gelatins "of a uniform molecular weight," and therefore fails to anticipate claim 4.

Amended claim 12 recites "[a] recombinant gelatin composition consisting essentially of recombinant gelatin polypeptides of a uniform molecular weight." As noted above, Wunderlich fails to disclose recombinant gelatins "of a uniform molecular weight." For at least this reason, Wunderlich does not anticipate amended claim 12.

Finally, claim 90 is amended above to recite "[a] pharmaceutical composition comprising a recombinant gelatin and a pharmaceutically acceptable excipient, wherein the recombinant gelatin consists recombinant gelatin polypeptides of a uniform molecular weight." As described, *supra*, Wunderlich does not disclose recombinant gelatins "of a uniform molecular weight," and, therefore, does not anticipate claim 90 as amended above.

As Wunderlich does not anticipate amended claims 4, 12, and 90, withdrawal of the rejection of these claims as being anticipated under 35 U.S.C. § 102(e) by Wunderlich is respectfully requested.

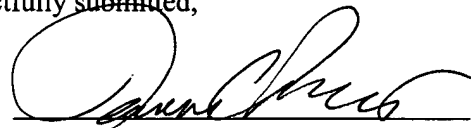
CONCLUSION

The Examiner's withdrawal of the previous rejections and objections and the Examiner's indication that claims 5, 6, 30, 43-45, 47, 48, 50, 54-57, 59, 62, 64-68, 70-73, 76-83, and 92-94 are allowable are much appreciated. Further, the indication of the Examiner and Supervisory Examiner Weber in the interview of 7 December 2004 that the claims as amended herein would be allowable is greatly appreciated. In view of the above amendments and arguments, Applicants believe that the present application is now in condition for allowance.

Please call Applicant's Attorney directly at 650-866-7254 with any questions regarding this communication.

Respectfully submitted,

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